Arent Fox
ATTORNEYS AT LAW

Arent Fox Kintner Plotkin & Kahn, PLLC
1050 Connecticut Avenue, NW
Washington, DC 20036-5339
Phone 202/857-6000
Fax 202/857-6395
www.arentfox.com

Peter S. Reichertz
202/857-6378
reicherp@arentfox.com

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BY HAND

Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket 78N-036L
Laxative Drug Products for Over-The-Counter Human Use
Comment CP20
Response to FDA Letters of
December 13, 1999 and September 28, 2000

Dear Sir/Madam:

We represent C.B. Fleet Company, Incorporated, of Lynchburg, Virginia ("Fleet"). This letter is in response to the above-referenced communications from the Agency, in which the Agency requested additional data supporting the safety and effectiveness of a tap water enema as a final cleansing step in bowel cleansing systems.

On June 9, 1995, Fleet had submitted the above-referenced Citizen Petition requesting inclusion in the Final Monograph on OTC Laxative Drug Products for Human Use ("Final Monograph") several bowel cleansing kits, among them Fleet® Prep Kit™ 2 and Fleet® Prep Kit™ 5. Those bowel cleansing kits used a tap water enema as a final cleansing step. Please note that Fleet has since discontinued Fleet® Prep Kit™ 5, so the information provided herein is limited to Fleet® Prep Kit™ 2. As such, Fleet by this submission amends its January 5, 1995, submission and deletes any request that the bowel cleansing system identified as Fleet® Prep Kit™ 5 be included in the Final Monograph, and limits its request to inclusion of Fleet® Prep Kit™ 2.

Fleet® Prep Kit™ 2 consists of:

One Fleet® Phospho-Soda®
(Sodium Phosphates Oral Solution)

4 Fleet® Bisacodyl Tablets

1 Fleet® Bagenema®

to be used sequentially in the above-referenced order "for use as a bowel cleansing regimen in preparing patients for surgery or for preparing the colon for x-ray or endoscopic examination". As requested, one sample of the product has been submitted with this submission.

In addition, a sample of Fleet® Bagenema®, which is the enema bag used with tap water as a final cleansing step, has been submitted. That product is separately marketed as a medical device pursuant to 21 C.F.R. §876.5210 (2000 edition). That regulation provides:

§ 876.5210 Enema kit.

(a) *Identification.* An enema kit is a device intended to instill water or other fluids into the colon through a nozzle inserted into the rectum to promote evacuation of the contents of the lower colon. The device consists of a container for fluid connected to the nozzle either directly or via tubing. This device does not include the colonic irrigation system (§876.5220).

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §876.9. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180 of this chapter, with respect to general requirements concerning records, and §820.198 of this chapter, with respect to complaint files.

That product (which is exempt from 510(k) notification) is also to be used with tap water to cleanse the colon. As such, the use of a tap water enema as a medical device is recognized by the Agency as a safe, effective means of evacuating the contents of the colon.

With this preface in mind, Fleet responds to each of the Agency's requests as follows. Please note that, for ease of reference, where necessary, an appropriate bibliography is attached for each section. In addition, the response to each question is included in a separately tabbed section responsive to each of the nine FDA questions.